REMARKS

Claims 1-69 were pending at the time of the Office action. Claims 2, 7-46, 48, 49, and 52-69 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 4-6 and 47 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 3-6, 47, 50, and 51 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Claims 1, 3-6, 47, 50, and 51 stand rejected under 35 U.S.C. § 112, first paragraph, for insufficient scope of enablement. Applicants address each of these rejections as follows.

Claim Amendments

Claims 4-6 and 47 have been amended to correct minor informalities. No new matter has been added by the present amendment. Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 4-6 and 47 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner notes that each of these claims contains phrases that lack proper antecedent basis. Applicants have amended the claims to correct these informalities and, as such, the rejection of claims 4-6 and 47 under 35 U.S.C. § 112, second paragraph, may now be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1, 3-6, 47, 50, and 51 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states (pages 5-6) that "regarding claims 1, 3-6, and 47, the specification has adequately described in terms of their complete structure two nucleic acids – nucleic acids comprising SEQ ID

NO: 1 and nucleic acids consisting of SEQ ID NO: 2. Regarding claims 50 and 51, the specification has disclosed only one full length mRNA that is the mRNA sequence of the cDNA of SEQ ID NO: 1..." (emphasis added). Applicants respectfully disagree.

Turning first to claims 1, 3-6, and 47, the Examiner states (page 4) that these claims "encompass nucleic acids that contain the 1036 nucleotides of SEQ ID NO: 2 flanked at the 5' end by nucleotides of any length and identity. As such, to the extent that the claims encompass PINX1 polynucleotides comprising SEQ ID NO: 2, the claims define only a portion of PINX1 but do not define the complete structure of PINX1" (emphasis added).

Applicants submit that the present specification provides a written description of the invention of claims 1, 3-6, and 47 in sufficient detail to satisfy the standard set forth by the Patent Office in its Written Description Guidelines and by the Federal Circuit in *Lilly*. In particular, *Lilly* specifically states that the written description of a genus of DNA may be achieved by a "recitation of structural features common to members of the genus." *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1159, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). The Guidelines for Examination of Patent Applications Under 35 U.S.C. 112 ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) similarly state:

> The written description requirement for a claimed genus may be satisfied... by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus...

Applicants further submit that in the section entitled "Responses to Specific Comments" published in the Federal Register with The Guidelines for Examination of Patent Applications Under 35 U.S.C. 112 ¶1, "Written Description" Requirement, it is noted that "there is no basis for a *per se* rule requiring disclosure of complete DNA

sequences or limiting DNA claims to only the sequence disclosed."

In view of the standards described above, claims 1, 3-6, and 47 clearly set forth sufficient structural identifying characteristics, in combination with the functional requirement of telomerase inhibition. The specification teaches the sequence of SEQ ID No: 2, which represents a partial structure of each polynucleotide encompassed by the claimed genus. Each member of the claimed genus must include SEQ ID No: 2 as part of its structure because the presence of SEQ ID No: 2 defines the scope of the claimed genus. Because the sequence of SEQ ID No: 2 is a structural feature common to all members of the claimed genus and the specification describes the complete structure of SEQ ID No: 2, Applicants were in possession of the claimed invention at the time the application was filed.

Turning next to claims 50 and 51, the Examiner states (page 5) that "[t]he claims define the mRNA in terms of the fact that it is transcribed from SEQ ID NO: 1. However, the claims do not define the complete structure of the mRNA... and [t]he claims thereby include antisense oligonucleotides fully complementary to both naturally occurring and non-naturally occurring mRNA, including potential splice variants and fragments, that may be transcribed from SEQ ID NO: 1."

Applicants respectfully disagree. Applicants note that claims 50 and 51 define the mRNA as a sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No: 1. SEQ ID No: 1 is a structural feature common to the polynucleotides of claims 50 and 51, and defines and limits the structure of the polynucleotide from which the mRNA of the present invention is transcribed. As such, Applicants submit that the complete structure of the mRNA of claims 50 and 51 is clearly defined.

Applicants respectfully request that the written description rejections be withdrawn.

Enablement

Claims 1, 3-6, 47, 50, and 51 also stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states (page 10) that "the specification, while being enabling for isolated polynucleotides comprising SEQ ID NO: 1 and isolated polynucleotides consisting of SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides comprising SEQ ID NO: 2 or antisense polynucleotides fully complementary to any mRNA transcribed from SEQ ID NO: 1." Applicants respectfully disagree.

With respect to the rejection of claims 1, 3-6, and 47, and as noted above, the specification teaches the sequence of SEQ ID No: 2, which represents a partial structure of each polynucleotide encompassed by the claimed genus (e.g., isolated PinX1 polynucleotides comprising the sequence of SEQ ID No: 2). Each member of the claimed genus includes SEQ ID No: 2 as part of its structure because the presence of SEQ ID No: 2 defines the scope of the claimed genus. The generation of sequences within the claimed genus would not require undue experimentation, as such a practice is routine to one of skill in the art. Claims 1, 3-6, and 47 satisfy the enablement requirement.

The Examiner also states (page 11) that "[c]laims 50 and 51 are drawn to pharmaceutical compositions comprising an antisense oligonucleotide fully complementary to 'the mRNA sequence transcribed from a polynucleotide comprising SEQ ID NO: 1'... [but that] the claims do not define the complete structure of the mRNA." Claims 50 and 51 define the mRNA as a sequence transcribed from a polynucleotide comprising the sequence of SEQ ID No: 1. SEQ ID No: 1 is a structural feature common to the polynucleotides of claims 50 and 51, and defines and limits the structure of the polynucleotide from which the mRNA of the present invention is transcribed. Indeed, one of skill in the art would be able to generate mRNA sequences using SEQ ID No: 1 as a template based on the teachings of the specification. As such, Applicants submit that claims 50 and 51 satisfy the enablement requirement.

The Examiner further notes that claim 4 is drawn to a host cell comprising a DNA vector comprising a polynucleotide comprising SEQ ID NO: 1 or 2, but that the claim does not recite that the host cell is isolated. To expedite prosecution, Applicants have amended claim 4 to specify that the host cell is isolated.

For these reasons, Applicants respectfully request that enablement rejections be withdrawn.

CONCLUSION

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including June 12, 2008, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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